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13
14 UNITED STATES DISTRICT COURT
15 SOUTHERN DISTRICT OF CALIFORNIA
16

17 GEN-PROBE INCORPORATED,

18 Plaintiff,

19 v.

20 VYSIS, INC.,

21 Defendant.
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27
28

No. 99CV2668 H (AJB)

**PLAINTIFF GEN-PROBE INCORPORATED'S
REPLY MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT OF MOTION FOR
PARTIAL SUMMARY JUDGMENT**

Date: June 8, 2001
Time: 10:30 a.m.
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1 While characterizing Gen-Probe's motion as "frivolous," (Vysis Opp. Memo at 2:1), Vysis
2 does not seriously dispute the facts relevant to the Court's determination of Gen-Probe's motion.¹
3 Significantly, Vysis admits that Gen-Probe does not literally infringe the claims of the '338 patent
4 if the claims cover only non-specific amplification. (Undisputed Fact No. 28.)

5 Vysis makes two primary arguments to support its assertion that the '338 patent covers
6 specific amplification. First, Vysis contends that a single parenthetical statement in Example 5 of
7 the specification discloses specific amplification. However, each inventor has *admitted* that
8 Example 5 discloses only *non-specific* amplification. Further, the patent expressly states that in
9 the method of Example 5 (and associated Figure 5) the target nucleic acids are replicated "non-
10 specifically."

11 Second, Vysis contends that the prosecution history demonstrates that the patent
12 encompasses specific amplification methods such as PCR. However, the self-serving arguments
13 first made by Vysis' patent prosecution counsel in *December 1995*, eight years after the patent
14 application was first filed, cannot expand the description of the invention originally set forth in the
15 patent specification.

16 **I. THE CLAIMS OF THE '338 PATENT MUST BE CONSTRUED BASED ON THE**
17 **"WRITTEN DESCRIPTION" OF THE INVENTION SET FORTH IN THE**
18 **SPECIFICATION**

19 The specification of every patent must "contain a written description of the invention." 35
20 U.S.C. § 112; *see also* 3 Chisum on Patents, Adequate Claims § 7.01 *et seq.* The written
21 description requirement protects the public from over-claiming by inventors who have not made an
22 invention that is commensurate with the scope of their claims: "The purpose of this [written
23 description] provision is to ensure that the scope of the right to exclude, as set forth in the claims,
24 does not overreach the scope of the inventor's contribution to the field of art *as described in the*
25 *patent specification.*" *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000) (emphasis
26 added). Thus, an inventor is entitled to claim only the invention described in the specification.

27 ///

28 ¹ Vysis does not dispute Facts 1, 3, 6, 7, 10-15, 17, 21, 22, or 26-28. Vysis "disputes" Facts 5, 8,
9, 16, 18 only on the ground that Example 5 of the patent discloses specific amplification.

1 The purpose of claim construction is to interpret the normally terse language found in
2 patent claims. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1580
3 (Fed. Cir. 1991). Because of the written description requirement, the patent specification is the
4 single best guide to the meaning of a disputed term and is usually dispositive. *Vitronics Corp. v.*
5 *Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). In claim construction, the court gives
6 effect to the written description by determining what a person skilled in the art would have
7 understood to be the invention described in the specification, as of the *earliest* date to which the
8 patent claims priority. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 985-986 (Fed.
9 Cir. 1995), *aff'd*, 517 U.S. 370 (1996); *accord*, *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133
10 F.3d 1472, 1478 (Fed. Cir. 1998). Claims in a patent may not be validly construed to be broader
11 than the supporting disclosures of the specification. *Gentry Gallery, Inc. v. Berkline Corp.*, 134
12 F.3d 1473, 1479-80 (Fed. Cir. 1998).

13 **II. THE SPECIFICATION OF THE '338 PATENT TEACHES ONLY THAT A**
14 **TARGET CAPTURE STEP WILL IMPROVE *NON-SPECIFIC* AMPLIFICATION**

15 The '338 patent is directed solely to methods of non-specific amplification. The patent
16 specification teaches that a target capture step improves non-specific amplification. The
17 specification describes only the combination of target capture and non-specific amplification. The
18 patent does *not* describe specific amplification methods and does not teach any benefits from the
19 combination of target capture and specific amplification. The specification refers to specially
20 tailored primers only to state that they are not necessary when an initial target capture step is used².
21 The specification is entirely consistent with the inventors' testimony that they were searching for,
22 and invented, *alternatives* to specific amplification (see discussion, *infra*, section III).

23 In an effort to identify *some* reference to specific amplification in the patent, Vysis can
24 only point to a single parenthetical sentence at the end of Example 5 of the '338 patent³. Vysis

25
26 ² The invention of the '338 patent cannot encompass methods that the specification states are
27 unnecessary due to the benefits of a target capture step prior to amplification. *Evans Medical Ltd.*
28 *v. American Cyanamid Co.*, 11 F. Supp. 2d 338, 355-56 (S.D.N.Y. 1998), *aff'd without op.*, 215
F.3d 1347 (Fed. Cir. 1999).

³ Vysis admits that six of the seven examples in the patent do not disclose specific amplification.
(Undisputed Facts Nos. 3, 5-7, 10-13.)

1 argues that this parenthetical statement discloses use of a specific capture probe as a specific
2 primer, and that thus Example 5 discloses "specific amplification." (Vysis Opp. Memo at 9-10.)
3 However, Vysis' effort to expand the import of this "alternative," parenthetical statement is
4 contradicted by the clear language of the specification and the inventors' testimony about what is
5 disclosed in Example 5.

6 It is beyond reasonable dispute that Example 5 teaches only the combination of target
7 capture with *non-specific* replication. Example 5 is set forth in three paragraphs of text beginning
8 at col. 31, line 24 of the '338 patent. The first paragraph consists of a single sentence that states,
9 concisely and exactly, what the example teaches:

10 In this example, both *non-specific* replication of target DNA and
11 transcription of that DNA are used to amplify capture target DNA.

12 (Exh. 8, at col. 31, ll. 24-54, emphasis added.) The second paragraph of example 5 provides the
13 details of a particular method, and teaches the use of *random* (e.g., non-specific) primers, and non-
14 specific transcription, in the amplification process used in the method. (Exh. 8, at col. 31, ll. 31-
15 33.) As a result of these explicit statements, a person skilled in the art would understand that
16 Example 5 discloses a non-specific method of amplification.

17 This understanding is reinforced by the fact that Example 5 refers to and incorporates
18 Figure 5 of the drawings included in the patent. (Exhibit 8 at col. 31, l. 28.) The drawings,
19 including Figure 5, are discussed and described in the text of the patent specification:

20 In Step 3 of FIGS. 4, 5 and 6, the isolated target is *non-specifically*
21 amplified to form a multitude of amplification products.

22 (*Id.* at col. 15, ll. 56-58, emphasis added.) Thus Vysis' present contention that Example 5 teaches
23 specific amplification is contrary to the multiple descriptions of that example within the
24 specification.

25 In light of the clear language of the specification, inventors Jon Lawrie and Donald Halbert
26 admitted that Example 5 discloses and teaches only non-specific amplification:

27 Q. Looking at Example 5, Example 5 also refers to nonspecific
28 amplification, is that correct?

///

1 A. The first sentence says, "Nonspecific replication of target
2 DNA and transcription of that DNA are used to amplify captured
target DNA." So it does address amplification. . . .

3 Q. So Example 5 discloses a linear *nonspecific* method of
4 amplification?

5 A. Yes.

6 (Lawrie Depo. at 230:17 - 231:16 (Exhibit 9) (emphasis added).)

7 Q. At least as to the four -- the Examples 4 through 7, *is there*
8 *any information or reference with respect to those examples that*
you would characterize to suggest specific amplification?

9 A. To suggest specific amplification?

10 Q. Yes.

11 A. Not to my knowledge.

12 (Halbert Depo. at 94:1-7 (Exhibit 18)(emphasis added).) Dr. Richards reached the same
13 conclusion. (Richards Depo at 139:19 - 140:3 (Exhibit 10).)

14 Vysis' contention that Example 5 discloses specific amplification is based on the statement,
15 midway through the third (and final) paragraph of Example 5 that: "(Alternatively, the double
16 stranded DNA can be formed by synthesis starting from capture probe a.)" Vysis' retained expert,
17 Dr. David Persing opines that Example 5 discloses specific amplification. However, the mere
18 statement that "the double-standard DNA can be formed by synthesis starting from capture probe
19 a" does not teach that such synthesis constitutes specific amplification nor that the capture probe
20 functions as a specific primer. The term "specific" does not appear in the statement, nor anywhere
21 else in the patent, with respect to primers or amplification. Moreover, inventor Lawrie admitted
22 that use of a capture probe in connection with non-specific amplification does not transform the
23 amplification step into a method of specific amplification such as PCR:

24 Q. Can you recall whether anyone else -- that you understood
25 that anyone else was concerned about whether the use of specific
26 capture probes made any work that Gene-Trak was doing too close
27 to Cetus's PCR method?

28

///

1 A. Yeah. *Capture probes are not the same as Cetus; so I don't*
2 *think, my definition of capture probes is not Cetus. Even today I*
3 *would say it is different.*

(Lawrie Depo. at 122: 6-17 (Exhibit 16) (emphasis added).)

4 The "alternative," parenthetical statement in Example 5 is the *only* basis for Vysis'
5 contention that specific amplification is disclosed anywhere in the specification. However, The
6 specification (and the inventors) clearly characterize Example 5 and Figure 5 as describing only
7 non-specific amplification. Therefore, the '338 patent does not describe, either in Example 5 or
8 anywhere else, methods that combine target capture with specific amplification. The patent claims
9 cannot literally encompass methods that are not described in the specification as part of the
10 invention made by the inventors.

11 **III. TESTIMONY FROM KEY WITNESSES CLEARLY ESTABLISHES THE SCOPE**
12 **OF THE INVENTION DISCLOSED IN THE '338 PATENT**

13 In deposition, inventor Jon Lawrie clearly testified that his invention did not include
14 methods of specific amplification such as PCR. Dr. Lawrie explained that the inventors were
15 seeking *alternatives* to PCR. (Gen-Probe Memorandum at 20-21.)

16 Seeking to distance itself from its own inventor, Vysis argues that inventor Lawrie's
17 subjective intent "is simply irrelevant to the claim construction issue." (Vysis Opp. Memo. at
18 14:11.) However, the interpretation to be given a term in a patent claim can *only* be determined
19 and confirmed with a full understanding of what the inventors actually invented and intended to
20 include within the claim. *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377, 1384
21 (Fed. Cir. 1999); *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir.
22 1998). It is inappropriate to disregard relevant evidence on any issue in any case, patent cases
23 included. *Netword LLC v. Centraal Corp.*, 242 F.3d 1347, 1355 (Fed. Cir. 2001); *Stratoflex, Inc.*
24 *v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). The testimony of inventors is expressly
25 recognized to be of value to the court in the claim construction process. *Voice Technologies*
26 *Group, Inc. v. VMC Systems, Inc.*, 164 F.3d 605, 616 (Fed. Cir. 1999) (holding that the district
27 court erred by excluding a deposition and video demonstration by the patent's inventor); *Gentry*
28 *Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir.1998); *Evans Medical Ltd. v.*

1 *American Cyanamid Co.*, 11 F. Supp.2d 338, 350-51 (S.D.N.Y. 1998), *aff'd without op.*, 215 F.3d
2 1347 (Fed. Cir. 1999) (claim construction based on intrinsic evidence was supported by the
3 testimony of the inventor "against his own interest," which is "the best and most reliable extrinsic
4 evidence").

5 What *is* forbidden is permitting the inventors to seek to *expand* the scope of patent claims,
6 by testimony as to their subjective intent, over the description set forth in the specification. *See*
7 *Markman*, 52 F.3d at 985. Dr. Lawrie's testimony about the actual invention does not expand the
8 scope of the patent - his testimony aids in determining the actual scope of the invention and in
9 limiting the scope of the patent in the face of Vysis' current effort to retroactively expand it.

10 Subsequent depositions of other inventors confirm that the invention described in the '338
11 patent does not include the combination of target capture with specific amplification. For
12 example, Walter King was deposed on April 17, 2001. (Dr. King is the only one of the inventors
13 still employed by Vysis.) Dr. King testified that that the invention claimed in the patent was
14 conceived at a single meeting of the inventors in 1986 and he further testified that specific
15 amplification was not discussed at that meeting:

16 Q. You didn't talk about target capture and specific
17 amplification in your meeting in 1986, correct? That's still your
18 testimony?

19 A. Yes.

20 Q. You didn't have any further involvement with respect to any
21 of the work that related to this patent application until you signed the
22 oath in December of 1997 [sic: 1987], correct?

23 A. Yes.

24 (King Depo. at 184:1-16 (Exhibit 17).)

25 Dr. King also confirmed that the reason specific amplification methods such as PCR were
26 not discussed at the meeting was that the inventors were trying to find ways *to get around* PCR.
27 (King Depo at 185:23 - 186:6.) In his deposition testimony, Dr. King repeatedly stated the
28 inventors' purpose:

///

1 Q From a high level perspective, what were the discussion
2 topics addressed during this meeting?

3 A. I think that at the highest level we were looking for
4 amplification methods *that did not involve PCR amplification.*

(King Depo. at 45:10-15 (Exhibit 17) (emphasis added).)

5 Q. Okay. So the purpose - the general purpose of the discussion
6 as I understand it that took place at Gene-Trak among the four
7 doctors was to identify - in general identify an amplification
8 technique that would amplify low concentrations of target nucleic
9 acids in a sample, correct?

10 A. Yes.

11 Q. And as I understand your testimony, you wanted to find a
12 technique *that was different from PCR*, correct?

13 A. Yes.

14 (King Depo. at 47:9-20 (Exhibit 17) (emphasis added).)

15 When Dr. King he signed the oath in support of the patent application, he did not
16 understand that the inventors claimed as their invention the combination of target capture and
17 specific amplification:

18 Q. Okay. At the time that the four of you participated in the
19 filing of the original application that led to the issuance of -- that
20 disclosed amplification techniques that led to the issuance of the '338
21 patent, did you intend to claim the combination of target capture
22 with PCR?

23 A. *I don't have any recollection of that being tied together with
24 PCR.*

25 (King Depo. at 136:14-21 (Exhibit 17) (emphasis added).)

26 Q. Did you believe that you had come up with the idea of
27 combining target capture with PCR at any time in the work that was
28 associated with the 338 patent?

A. *Not specifically with PCR, no.*

Q. Did any of the other three identified inventors: Drs. Lawrie,
Halbert or Collins ever indicate to you that - at any point in time,
that they ever believed that one of them had come up with the idea of
combining target capture with PCR?

A. No, I don't recall.

1 (King Depo. at 1339:21 - 140:7 (Exhibit 17) (emphasis added).)

2 Vysis also argues that Dr. Lawrie testified “that he believed that the invention of the ‘338
3 patent is not limited to nonspecific amplification.” (Vysis Opp. Memo. at 14:14-15.) The question
4 asked by Vysis’ counsel concerned the patent application, *not* the invention itself. (Exhibit H.)
5 But the inventors’ testimony is relevant only to show what their actual *invention* was, not what
6 they think the *patent application* disclosed. Testimony from the inventors about the patent
7 application that seeks to expand what they actually invented is exactly the type of inventor
8 testimony that is irrelevant to the claim construction process. *See Markman*, 52 F.3d at 985. The
9 inventors’ current understanding of the *patent* is irrelevant. Interpretation of the patent is an issue
10 of law for the court. What matters is the inventors’ understanding of what they actually invented,
11 and on that issue it is clear they believe they invented the combination of target capture and
12 *non-specific* amplification.

13 The best evidence on the question of how a person skilled in the art understood the
14 invention of the ‘338 patent at the time the first application for the patent was filed is set forth in
15 the December 1989 description of the invention by Dr. James Richards:

16 Cetus, Sibia/Salk, Biotechnica, etc. all claim **specific** primers for
17 amplification whereas the present invention claims uses of the
18 opposite, namely, **non-specific** primer or promoters. . . .

19 (Exhibit 1, emphasis added.) Dr. Richards was clearly a person skilled in the art of nucleic acid
20 hybridization as of December 1989. All witnesses in the case agree that Dr. Richards was
21 knowledgeable with respect to both nucleic acid hybridization and the technologies available to
22 Gene-Trak. (Smith Depo. at 21:12 - 22:9 (Exhibit 14); Ward Depo at 15:25 - 16:15 (Exhibit 15);
23 Janiuk Depo. at 26:22 - 27:24 (Exhibit 13).) Dr. Richards’ December 1989 analysis was made
24 pre-litigation, when he had no motivation to do anything other than use his considerable education
25 and experience, including discussions with the inventors and with patent counsel, to accurately
26 describe the invention.

27 Vysis challenges Dr. Richards’ statements on the ground that when he made them “he had
28 not even read the patent application.” However, on November 14, 1989, only a month before Dr.
Richards recorded his analysis of the pending patent application, he requested a copy of the

1 application for review and it was sent to him by Gene-Trak's patent counsel. (Nov. 14, 1989
2 Letter (Exhibit 11); Janiuk Depo. at 56-57 (Exhibit 13).) At the time of his deposition, Dr.
3 Richards could not *recall* having read the patent application twelve years earlier, but the
4 application was sent to him in November 1989 and his December 1989 letter demonstrates his
5 familiarity with the pending application⁴.

6 Vysis also challenges the import of Dr. Richards' statements on the grounds that he only
7 "worked in business development." (Vysis Opp. Memo at 14:20.) However, this
8 mischaracterization of Dr. Richards' education, experience and responsibilities is unwarranted⁵.

9 IV. NOTHING IN THE PROSECUTION HISTORY EXPANDS THE SCOPE OF THE 10 INVENTION

11 As discussed above, the '338 patent teaches that a target capture step improves non-specific
12 amplification. The patent describes only non-specific amplification methods. The patent does *not*
13 refer to specific amplification and does not teach any benefits from the combination of target
14 capture and specific amplification. The inventors have admitted they did not invent a method that
15 combines target capture with specific amplification, and Dr. Richards' letter confirms that one
16 skilled in the art did not understand the invention to encompass specific amplification.

17 Faced with this overwhelming evidence, Vysis contends that the "prosecution history"
18 shows that the invention includes specific amplification. However, in this case the prosecution
19 history for the '338 patent does not add anything to the claim construction process.

20 For purposes of claim construction, the patent's claims, specification, and prosecution
21 history are considered to be "intrinsic evidence." Within this intrinsic evidence, "there is a
22 hierarchy of analytical tools." *Digital Biometrics Inc. v. Identix Inc.*, 149 F.3d 1335, 1344 (Fed.

23
24 ⁴ Moreover, if Dr. Richards did not read the application, his only other sources of information were
25 very reliable ones -- inventor Jon Lawrie and Gene-Trak's patent counsel, Tony Janiuk. (Richards
26 Depo. at 152:5-13; 186:11-21 (Exhibit 10).)

27 ⁵ Dr. Richards received a Ph.D. in Microbiology and Biochemistry from Southern Illinois
28 University. (Richards Depo., Exh. 10, at 7:17-20.) He managed Gene-Trak's technology assets
and technology needs. (*Id.* at 44:18 - 45:9; 47:22 - 48:24.) He was a member of the Gene-Trak
patent committee and discussed patents with Gene-Trak's patent counsel. (*Id.* at 150:15-21.)
When presentations on patent matters, including target capture patents, were made to the Gene-
Trak partnership committee and to the Gene-Trak scientific advisory board, Dr. Richards made
those presentations. (*Id.* at 60:8-13; 82:3-6; 150:9-14; 151:1-4.)

1 Cir. 1998). *Accord, Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).
2 The sources are considered, in descending order of weight and importance: (1) the claim language
3 itself; (2) the specification of the patent; and (3) the prosecution history. *Digital Biometrics,*
4 *supra*, 149 F.3d at 1344. *See also McKinley v. Franklin Sports, Inc.*, 45 F.Supp.2d 1141, 1143
5 (prosecution history is “tertiary” consideration).

6 As recognized in *Vitronics Corp.*, the patent specification “usually . . . is dispositive.”
7 *Vitronics*, 90 F.3d at 1582. The prosecution history cannot expand what was originally disclosed
8 in the “written description” of the invention set forth in the specification, and claims may not be
9 interpreted to be broader than what was described in the specification.⁶ When the specification
10 establishes the meaning for a term without ambiguity or incompleteness, there is no need to search
11 further for the meaning of the term. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1472,
12 1478 (Fed. Cir. 1998).

13 Although Vysis urges the court to consider the prosecution history, it does not provide any
14 guidelines about *how* the prosecution history is properly used in claim construction. In fact,
15 prosecution history is relevant to claim construction when the patent applicant, in the course of
16 patent prosecution, agreed to limit the scope of its claims or disclaim certain subject matter in
17 order to obtain allowance of the patent. “The prosecution history *limits* the interpretation of claim
18 terms so as to exclude any interpretation that was *disclaimed* during prosecution⁷.” *Southwall*
19 *Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995), *cert. denied*, 516 U.S.

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21
22 ⁶ In particular cases prosecution history may add nothing to the claim construction process. *See,*
23 *e.g., SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1340
24 (Fed. Cir. 2001)(“There is nothing pertinent to this issue [of claim construction] in the prosecution
25 history”); *Mantech Environmental Corp. v. Hudson Environmental Services Inc.*, 152 F.3d 1368,
26 1370 n.6, 1374 n.10 (Fed. Cir. 1998) (“There is no relevant prosecution history”). In this case the
27 specification clearly establishes the scope of the invention. The prosecution history does not
28 contribute to claim interpretation.

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31 ⁷ In practice, there is no meaningful distinction between the use of prosecution history in claim
32 interpretation and the operation of “prosecution history estoppel.” *HBB Limited Partnership v.*
33 *Ford Motor Co.*, 1996 U.S. Dist. Lexis 4047 at 19-20 (N.D. Ill. 1996); *Abtox, Inc. v. Exitron*
34 *Corp.*, 899 F.Supp. 775, 781 (D. Mass 1995). *See also McGill Inc. v. John Zink Co.*, 736 F.2d 666,
35 673 (Fed. Cir. 1984). Both applications of the prosecution history are triggered by concessions
36 made in order to obtain the patent. *HBB Limited Partnership v. Ford Motor Co.*, 1996 U.S. Dist.
37 Lexis 4047 at 20 (N.D. Ill. 1996).

1 987 (1995)(emphasis added)⁸. Therefore, “The prosecution history is, in most instances, cited
2 *against* a broad interpretation later asserted by the patent owner,” 5A Chisum on Patents,
3 Interpretation of Claims, § 18.03[d] at 18-117 (2000), because “the patentee has disclaimed or
4 disavowed a certain scope or definition for the purpose of escaping rejection by the PTO.”
5 *McNeil-PPC, Inc. v. Bayer Corp.*, 2000 U.S. Dist. Lexis 16431 at 16 (E.D. Pa. 2000).

6 In this case, Vysis does not and cannot cite any action which it took to narrow the claims
7 and specification in order to avoid prior art references and obtain allowance of the patent. There is
8 simply nothing in the prosecution history that is cognizable in the claim construction process in
9 this court.

10 Instead of citing relevant prosecution history in accordance with the rules established by
11 applicable precedent, Vysis seeks to stand the rules of construction on their head and *expand* the
12 written description of the invention set forth in the specification based simply on argument of
13 counsel in the course of patent prosecution. Self-serving statements of Vysis’ patent counsel,
14 which were made late in the course of patent prosecution in an effort to expand the original
15 specification based on post-filing developments, are not “prosecution history” for purposes of
16 claim construction. Such belated argument of counsel cannot expand the scope of the invention as
17 described in the patent application. The written description requirement of 35 U.S.C. § 112
18 preempts any such “bootstrapping” use of the prosecution history. An inventor may not define
19 claim terms more broadly during prosecution, to cover developments that took place after the
20 patent application was filed, than those terms were defined in the patent application. *Schering*
21 *Corp. v. Amgen, Inc.*, 18 F. Supp. 372, 389-90, (D. Del. 1998), *aff’d*, 222 F.3d 1347, (Fed. Cir.
22 2000).

23 Vysis’ attempt to rely on its patent counsel’s arguments in the course of patent prosecution
24 must also fail because they were made *too late in time* to be relevant. In the claim construction
25 process, the Court seeks to determine how a person skilled in the art would have understood the
26

27 ⁸ *Accord, Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Spectrum International, Inc. v. Sterlite*
28 *Corp.*, 164 F.3d 1372, 1378-79 (Fed. Cir. 1998); *Zenith Lab., Inc. v. Bristol-Myers Squibb Co.*, 19
F.3d 1418, 1421 (Fed. Cir.), *cert. denied*, 513 U.S. 995 (1994); *Standard Oil Co. v. American*
Cyanmid Co., 774 F.2d 448, 452 (Fed. Cir. 1985).

1 invention described in the patent as of the date of the first relevant patent application. *Multiform*
2 *Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998); *Markman, supra*, 52 F.3d
3 at 985-986. Here, that date is December 21, 1987. ('338 patent at 1, (Exhibit 8); May 24, 2001
4 Banks Decl., ¶ 3.) Prosecution history may be an important source of intrinsic evidence in
5 interpreting claims if it contains *contemporaneous* exchanges between the applicant and the patent
6 examiner. *Desper Products Inc. v. QSound Labs Inc.*, 157 F.3d 1325, 1336 (Fed. Cir. 1998);
7 *Digital Biometrics Inc. v. Identix Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998). However, courts
8 must be skeptical when papers filed with the PTO years after an initial patent application are
9 offered to prove the understanding of those skilled in the art at the time the application was filed.
10 *See Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328 (Fed. Cir. 2000) (court could not
11 consider amended patent claims that did not appear in original application to show that inventor
12 was in possession of the invention subsequently claimed at the time original application was filed).

13 Vysis' first contention that its invention encompassed specific amplification methods such
14 as PCR was not made until December 1995, eight years after its first patent application was filed.⁹
15 This contention was first made in support of Vysis' *fourth* application¹⁰ for a patent on the
16 invention at issue. (Vysis Ex. E.) Eight years and four applications after its first filing, Vysis drew
17 a new patent examiner and argued for the first time that the invention was an *improvement to PCR*.
18 This contention, made only in the form of argument of counsel during patent prosecution, is
19 completely unsupported by the patent application, which contains no mention whatsoever of PCR.

20
21 ⁹ In its brief, Vysis describes its initial argument as to PCR as having been set forth in a paper filed
22 with the PTO "responding to November 5, 1992 Office Action." (Opp. Memo. at 5:17-18. By this
23 citation, Vysis attempts to hide the actual date of its argument to the PTO -- **December 5, 1995** --
24 almost 8 years after the first patent application was filed and three years after the PTO Office
25 Action to which it purported to respond. (Vysis Exhibit E.)

26 ¹⁰ Vysis did not respond to the PTO's November 1992 office action. As a result, its patent
27 application was abandoned as of February 5, 1993. (Exhibit 19.)

28 Vysis did not take any further steps to seek a patent for the invention until May 3, 1994, more than
one year after it abandoned the application, when Vysis petitioned the PTO to "revive" the patent
application. (Gen-Probe Exhibit 20.) That petition was denied by the PTO on the ground Vysis
had waited more than one year after abandonment to seek revival. (Gen-Probe Exhibit 21.) In
May 1994, Vysis filed a *fourth* application, an identical copy of the three prior applications. Vysis
made its first arguments addressed to PCR in support of this fourth application. (The relevant facts
pertaining to the prosecution are set forth in the Reply Declaration of Christine Gritzmacher
submitted concurrently herewith.)

1 The inventors never represented to the PTO under oath that their invention encompassed PCR.

2 The prosecution history arguments cited by Vysis are irrelevant because they are simply
3 the argument of counsel, first made in December 1995, more than 8 years after the invention is
4 alleged to have been made. Vysis' belated prosecution arguments cannot retroactively change the
5 patent specification, nor are they evidence of the understanding of persons skilled in the art as of
6 December 21, 1987.

7 The argument of counsel is not made more significant because it was successful in
8 persuading the PTO to modify the PTO's views of the patent's subject matter. The PTO employs a
9 very different mode of claim construction than is to be applied in litigation. *In re Zletz*, 893 F.2d
10 319, 321 (Fed. Cir. 1989). During prosecution in the PTO, the claims are interpreted as broadly as
11 possible and there the limitations of the specification are not read into the claims. *Id.* at 322.
12 *Accord, In re Morris*, 127 F.3d 1048, 1053-54 (Fed. Cir. 1997). In this Court, however, claims are
13 to be interpreted narrowly based on the disclosures of the specification. *Wang Laboratories, Inc. v.*
14 *America Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999).

15 Second, the PTO's comments on the nature of the invention receive no deference in this
16 Court. Claim construction is a pure question of law, even when it encompasses subsidiary factual
17 issues. *Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (*en banc*). Claim
18 interpretations are subject to de novo review, without deference to factual findings. *Id.* Deference
19 may certainly not be given to a PTO examiner's decision in the course of an *ex parte* proceeding.
20 *See id.*; *see also Quad Environmental Tech v. Union Sanitary Dist.*, 946 F.2d 870, 876 (Fed. Cir.
21 1991) (Patent validity issues are "ultimately for the courts to decide, without deference to the
22 ruling of the patent examiner.")

23 Third, where an examiner's statements, made in the course of an *ex parte* PTO proceeding,
24 are not persuasive in light of all the evidence before a court, the court should disregard the
25 examiner's statements, particularly when the court has received, in an adversary hearing, evidence
26 which was not before the patent examiner¹¹. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320,

27
28 ¹¹ Here, the patent examiner did not have access to the inventor testimony, the Richards letter, or
other relevant evidence, because Vysis did not submit such evidence and the *ex parte* nature of the
99CV2668 H (AJB)

1 1329 (Fed. Cir. 2000). See also *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d
2 1547, 1556 (Fed. Cir. 1997), abrogated on other grounds (standard of appellate review), *Cybor*,
3 138 F.3d at 1456.

4 Vysis' final prosecution history argument, that the PTO's rejection of the initial
5 applications as "obvious" in light of the PCR patent, does not in any way support the proposition
6 that the '338 patent encompasses PCR. In response to the invention of PCR, and in an effort to
7 engineer around it, Vysis sought to develop methods that used non-specific amplification with an
8 initial target capture step. Vysis sought to achieve target specificity by target capture rather than
9 by specific amplification primers. Inventor Lawrie himself was concerned that this use of specific
10 capture and non-specific amplification was "too close" to the PCR method invented by Kary
11 Mullis and others at Cetus Corp. (Lawrie Notes (Exhibit 12); Lawrie Depo. at 102:15-20 (Exhibit
12 16.) Vysis' initial applications were not rejected by the PTO because Vysis' claims encompassed
13 PCR, but because those claims were an "obvious" attempt to achieve the same result as PCR in a
14 different manner.

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26 PTO proceedings precluded any other party from participating. Vysis did not provide the patent
27 examiner in the original prosecution with any evidence that the inventors agreed that the invention
28 encompassed specific amplification. Nor has Vysis provided such evidence to the examiner in the
pending reissue proceeding. Vysis has relied solely on argument of counsel and has not submitted
depositions, declarations, or evidentiary documents.

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1 V. CONCLUSION

2 The '338 patent describes and encompasses only methods of non-specific amplification.
3 Gen-Probe's products do not incorporate non-specific amplification and the Motion for Partial
4 Summary Judgment should be granted.

5 Dated: June 1, 2001

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7 J. CHRISTOPHER JACZKO
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13 By: 
14 J. Christopher Jaczko

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12 Attorneys for Plaintiff
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13
14 UNITED STATES DISTRICT COURT
15 SOUTHERN DISTRICT OF CALIFORNIA

16
17 GEN-PROBE INCORPORATED,

18 Plaintiff,

19 v.

20 VYSIS, INC.,

21 Defendant.

No. 99CV2668 H (AJB)

**PLAINTIFF GEN-PROBE INCORPORATED'S
PROOF OF SERVICE**

Date: June 8, 2001
Time: 10:30 a.m.
Dept: Courtroom 1

PROOF OF SERVICE
(FRCP 5)

I am a citizen of the United States and a resident of the State of California. I am employed in San Diego, State of California, in the office of a member of the bar of this Court, at whose direction the service was made. I am over the age of eighteen years, and not a party to the within action. My business address is 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. On the date set forth below I served the documents described below in the manner described below:

1. **PLAINTIFF GEN-PROBE INCORPORATED'S REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT**
2. **REPLY DECLARATION OF CHRISTINE GRITZMACHER IN SUPPORT OF GEN-PROBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT**
3. **REPLY DECLARATION OF STEPHEN P. SWINTON IN SUPPORT OF GEN-PROBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT**
4. **REPLY DECLARATION OF DR. JOSEPH O. FALKINHAM IN SUPPORT OF GEN-PROBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT**
5. **REPLY DECLARATION OF R. WILLIAM BOWEN IN SUPPORT OF GEN-PROBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT**
6. **REPLY NOTICE OF LODGMENT OF EXHIBITS IN SUPPORT OF GEN-PROBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT**
7. **STIPULATION AND [PROPOSED] ORDER ALLOWING GEN-PROBE INCORPORATED TO FILE UNDER SEAL CERTAIN DOCUMENTS UPON WHICH IT RELIES TO SUPPORT ITS REPLY RE MOTION FOR PARTIAL SUMMARY JUDGMENT**

(BY U.S. MAIL) I am personally and readily familiar with the business practice of Cooley Godward llp for collection and processing of correspondence for mailing with the United States Postal Service, and I caused such envelope(s) with postage thereon fully prepaid to be placed in the United States Postal Service at Palo Alto, California.

(BY MESSENGER SERVICE) by consigning the document(s) to an authorized courier and/or process server for hand delivery on this date. See attached Proof of Personal Service.

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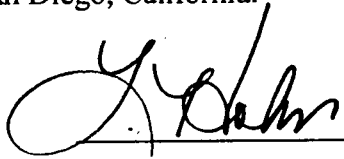
transmitted by facsimile to the offices of addressee(s) at the numbers listed below.

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on the following part(ies) in this action:

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Executed on June 1, 2001, at San Diego, California.



Liz Hoke

PROOF OF PERSONAL SERVICE

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I hereby declare:

I am employed in the City of San Diego, County of San Diego, California; I am over the age of eighteen years and not a party to the within cause; my business address is Knox Attorney Service, 2250 Fourth Avenue, San Diego, California 92103.

On June 1, 2001, I served the within document(s):

1. **PLAINTIFF GEN-PROBE INCORPORATED'S REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT**
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7. **STIPULATION AND [PROPOSED] ORDER ALLOWING GEN-PROBE INCORPORATED TO FILE UNDER SEAL CERTAIN DOCUMENTS UPON WHICH IT RELIES TO SUPPORT ITS REPLY RE MOTION FOR PARTIAL SUMMARY JUDGMENT**

on the interested parties in this action by personally hand delivering a copy of said document(s) to the address(es) listed below:

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Attorneys for Vysis, Inc.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on June 1, 2001.

SIGNATURE: _____

PRINT NAME: _____

CONFIRMATION REPORT - MEMORY SEND

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Cooley Godward LLP

ATTORNEYS AT LAW

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DATE: June 1, 2001

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Thomas W. Banks Finnegan Henderson Farabow	650 849 6600	650 849 6666

FROM: J. Christopher Jaczko PHONE: (858) 550-6027 REPLY FAX: (858) 453-3555
RE: Gen-Probe, Inc. v. Vysis, Inc.

NUMBER OF PAGES, INCLUDING COVER: 54	CLIENT NUMBER: 071907 202
ORIGINALS TO FOLLOW: Yes	

MESSAGE:

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12 Attorneys for Plaintiff
GEN-PROBE INCORPORATED

13
14 UNITED STATES DISTRICT COURT
15 SOUTHERN DISTRICT OF CALIFORNIA

16 GEN-PROBE INCORPORATED,

17 Plaintiff,

18 v.

19 VYSIS, INC.,

20 Defendant.

No. 99cv2668 H (AJB)

21
22
23 **REPLY NOTICE OF LODGMENT IN SUPPORT OF
PLAINTIFF GEN-PROBE INCORPORATED'S
MOTION FOR PARTIAL SUMMARY JUDGMENT**

Date: June 8, 2001
Time: 10:30 a.m.
Dept: Courtroom 1

24 **TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

25 **PLEASE TAKE NOTICE** that Plaintiff Gen-Probe Incorporated hereby lodges the following
26 exhibits in support of Gen-Probe Incorporated's Motion for Partial Summary Judgment:

27 **EXHIBIT 11:** A true and correct copy of a letter dated November 14, 1989 from Anthony J.

Janiuk to Dr. James C. Richards.

28 **EXHIBIT 12:** A true and correct copy of handwritten notes made by Jonathon Laurie, Ph.D.

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EXHIBIT 13: A true and correct copy of portions of the transcript of the deposition of Anthony J. Janiuk taken May 16, 2001. **[Filed Under Seal]**

EXHIBIT 14: A true and correct copy of portions of the transcript of the deposition of Alan E. Smith, Ph.D., taken May 17, 2001.

EXHIBIT 15: A true and correct copy of portions of the preliminary or "rough" transcript of the deposition of David Ward, Ph.D., taken May 18, 2001. **[Filed Under Seal]**

EXHIBIT 16: A true and correct copy of portions of the transcript of the deposition of Jon Laurie, Ph.D., taken February 15, 2001. **[Filed Under Seal]**

EXHIBIT 17: A true and correct copy of portions of the transcript of the deposition of Walter King, Ph.D., taken April 18, 2001. **[Filed Under Seal]**

EXHIBIT 18: A true and correct copy of portions of the transcript of the deposition of Donald Neil Halbert, Ph.D., taken April 19, 2001. **[Filed Under Seal]**

EXHIBIT 19: A true and correct copy of the Patent & Trademark Office's Notice of Abandonment of U.S. Patent application no. 07/944,505, dated June 16, 1993.

EXHIBIT 20: A true and correct copy of the Petition to Revive the [07/944,505] Application as Unintentionally Abandoned, dated May 3, 1994.

EXHIBIT 21: A true and correct copy of the Patent & Trademark Office's notice of denial of petition to revive [07/944,505] application, dated October 27, 1994.


EXHIBIT 22: Summary of prosecution history of United States Patent No. 5,750,338.

Dated: June 1, 2001

STEPHEN P. SWINTON
J. CHRISTOPHER JACZKO
COOLEY GODWARD LLP

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